UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Hon. Patti Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc., CIVIL ACTION NO. 06-11337-PBS	)	

MEMORANDUM BY THE UNITED STATES RELATING TO DOCUMENTS SUBMITTED FOR *IN CAMERA* REVIEW PURSUANT TO THE COURT'S ORDER OF NOVEMBER 9, 2007

The United States files this memorandum concurrently with its submission of 21 documents for *in camera* review by the Court. The 21 documents are those called for by Judge Saris's November 9, 2007 Order; namely those documents which Abbott has moved to compel the Government to produce that "relate to [the Government's] knowledge of a 'spread' for Abbott's drugs at issue in this litigation or its knowledge of Abbott's 'marketing the spread' for any of its drugs." *See Order Re: Objections to August 13, 2007 Order by Magistrate Judge Bowler*, November 9, 2007 (Dkt No. 4885) at 1.[1] The Court's Order of November 9 further directed the United States to explain why any documents it seeks to withhold should in fact be withheld under the "balancing test" applicable to documents withheld under the deliberative

[1] Abbott's original Motion to Compel sought the production of approximately 699 documents. Abbott's Motion was largely denied by the Magistrate Judge, although the Magistrate did order the United States to produce certain material implicating approximately 44 documents. *See Order of August 13, 2007* by Magistrate Judge Bowler. After both sides filed Objections to the Court's Order, Judge Saris directed that the Government submit documents from the two discrete categories noted above for *in camera* review, rather than for production directly to Abbott.

process privilege. The United States submits this memorandum in response to that direction from the Court.

Background - The Documents at Issue

The 21 documents implicated by the Judge Saris's November 9 Order, consist of two categories of material, one from HHS's Office of Inspector General (OIG), the second from the Centers for Medicare and Medicaid Services (CMS). The first category, comprising 19 documents, is made up of draft versions of two separate reports by OIG – a 1997 Report entitled "Excessive Medicare Reimbursement for Prescription Drugs"[2] and a 2001 report entitled "Medicaid's Use of Revised Average Wholesale Prices."[3] Although neither report mentions Abbott, both of them reference Vancomycin, which is a drug at issue in this litigation, and thus draft versions of the reports fall within the scope of Judge Saris's November 9 Order. Abbott already has the final versions of those reports, the final comments from CMS to OIG on the reports, as well as the information, including pricing data, contained in the OIG work paper files associated with the reports.

The second category contains two documents, each of which is a draft CMS memorandum. Both documents concern drug pricing information that had been compiled by the

[2] The Bates numbers for the draft versions of the 1997 report are: (1) HHD900 1270-1324; (2) HHD900 1349-1373; (3) HHD900 1374-1399; (4) HHD900 1411-1437; (5) HHD900 1438-1463; (6) HHD900 1476-1485; (7) HHD900 1486-1507; (8) HHD900 1515-1536; (9) HHD900 1537-1558; (10) HHD900 1563-1587; (11) HHD900 1588-1615; (12) HHD900 1621-1645; (13) HHD900 1656-1680.

[3] The Bates numbers for the draft versions of the 2001 report are: (1) HHD900-0622-0637; (2) HHD900 0638-0652; (3) HHD900 0653-0668; (4) HHD900 0669-0683; (5) HHD900 1209-1237; (6) HHD900 1238-1269.

Department of Justice (DOJ) in or around 1999 and 2000.[4] One draft memorandum contains a discussion of CMS policy options for using the pricing data acquired by DOJ.[5] The discussion of whether and how CMS should or could use the pricing information developed by DOJ implicates the governmental interests at the core of the deliberative process privilege – namely, the pre-decisional deliberations that are essential to informed agency decision-making. The second document is a draft version of a CMS program memorandum which would convey the agency's ultimate decision about how CMS's Medicare Carriers could use the prices compiled by DOJ as an alternative source for Average Wholesale Prices (AWPs) for certain drugs covered by the Medicare program. Abbott has the final, public, version of that memorandum which was issued in 2000 (Program Memorandum AB-00-86). Indeed, the list of drug prices compiled by DOJ in 1999/2000 has been publicly available since 2000. Although the draft memoranda do not mention Abbott, the list of DOJ-compiled prices includes Abbott drugs.

Given that Abbott has the final versions of both the OIG reports, which contain pricing information collected over the course of two OIG inspections (as well as associated inspection workpapers), and CMS Program Memorandum AB-00-86 with its appended list of drug prices collected by DOJ, defendant's need for the 21 draft documents submitted for review is virtually non-existent in comparison to the Government's interest in protecting the integrity of its

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[4] Theses documents bear the Bates numbers HHC902 0214-0244 and HHC9010689-0710.

[5] This document was imaged and bates-numbered in the manner in which it was maintained its original file. Likely due to the draft nature of the document, it is interspersed with pages which appear to have been generated in the printing process. In order to produce the document as maintained, we have produced these non-responsive print-out pages as well as the pages with the text of the memorandum and attachments.

deliberative processes. Any need Abbott may set forth for these documents is outweighed by the Government's interest in fostering the candid discussions instrumental to the agency's critical evaluation of its own programs (with respect to the draft OIG documents) and its policymaking processes (with respect to the draft memoranda relating to whether and how Medicare carriers could use an alternative source of pricing data). Accordingly, the United States' privilege assertion for both the draft inspection reports and the draft memoranda should be upheld in the face of Abbott's demand for the documents.

Application of the deliberative process privilege to the foregoing categories of documents will be further addressed below.

Argument

After concluding that the deliberative process privilege has been properly invoked, as the Court has done here, a court must balance the public interest in protection of the deliberative process against the particularized need for the information as evidence in the case before it. *See Comm. for Nuclear Responsibility, Inc. v. Seaborg,* 463 F.2d 788, 791 (D.C. Cir. 1971); *Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena,* 40 F.R.D. 318, 327 (D.D.C. 1966), *aff'd*, 384 F.2d 979 (D.C. Cir. 1967); *Scott v. PPG Indus., Inc.*, 142 F.R.D. 291, 294 (N.D. W. Va. 1992). To compel disclosure, the requesting party must make "a showing of necessity sufficient to outweigh the adverse effects the production would engender." *Carl Zeiss*, 40 F.R.D. at 328-29. When balancing the Government's interest in protecting its deliberative processes against an opponent's need for the evidence, the following factors should be considered:

> (i) the relevance of the evidence sought to be protected; (ii) the availability of other evidence; (iii) the 'seriousness' of the litigation and the issues involved; (iv) the role of the government in the litigation; and (v) the possibility of future

> timidity by government employees who will be forced to recognize that their secrets are violable.

In re Franklin Nat'l Bank Sec. Litig., 478 F.Supp 577, 583 (E.D.N.Y. 1979) (citations omitted).

An application of these factors to the documents submitted by the Government redounds heavily in favor of nondisclosure. Again, the documents at issue fall into two categories: (1) 19 draft versions of two OIG reports, and (2) a draft internal memorandum concerning whether CMS should use the AWP data assembled by DOJ and a draft version of CMS Program Memorandum AB-00-86 which instructed CMS Medicare Carriers about the availability of the DOJ data for setting allowable amounts for certain drugs.

Factor One - Relevance of the Protected Information

The draft documents submitted for in camera review do not contain relevant evidence. To the extent the factual information about drug prices is contained in the documents – whether they be the draft reports or the draft memoranda – that information has been released via the production of other documents, including the final versions of the inspection reports, the inspection work papers and the final version of the program memorandum with its appended price list. Any assessment of the relevance of the material that the United States has submitted for *in camera* review must be evaluated in the context of the information that Abbott already has in its possession.

The only additional information Abbott would obtain through the release of the these draft materials is the internal suggestions, proposed edits, and comments of OIG and CMS staff on various draft iterations of the two reports and program memorandum. None of these suggestions, edits, or comments represents a final agency decision about either the reports or the

memorandum. As the First Circuit made clear in *United States v. Lachman*, any interpretive issue relating to a statute or regulation is resolved through reference to the *official public record*. 387 F.3d 42, 54 (1st Cir. 2004). Any issue about Governmental intent, whether it be in changing a policy or refraining from a policy change, is not resolved by reference to the deliberations of individuals. Moreover, the Court has already issued a decision resolving the intent of the Government's AWP-based drug payment system. *See In Re Average Wholesale Price Litig.,* 460 F. Supp. 2d 277, 278 (D. Mass. 2006). In this situation, the proposed edits, marginalia, and the like contained in the draft documents are of no relevance to any legitimate issue in this case.

Factor Two - Availability of Other Evidence

As noted above, by withholding the draft documents in either of the two categories, the United States has not deprived Abbott of factual information relating to what the Government knew about Abbott's actual prices for its drugs. Such documents reflecting the Government's knowledge of Abbott's prices have been produced. Final versions of the reports at issue, as well as the final CMS comments on the reports and OIG's responses to CMS's comments have been publicly available since long before this lawsuit was filed. The United States has also produced non-privileged internal OIG work paper files for both the 1997 and 2001 reports. These work paper files include background material relating to the preparation of the reports, OIG's communications with outside sources of data and information, non-privileged internal OIG communications about the reports and the methods used to conduct the inspections, as well as the data upon which the reports were based. Abbott thus has access to the factual information acquired and used by OIG when preparing the reports, OIG's ultimate conclusions about that information (in the form of the final reports), and CMS's responses to OIG's information and

analysis. Abbott has also deposed the principal authors of the reports, and has been able to interrogate them regarding the facts they assembled during the inspections and the methods they employed to obtain the data reflected in the reports. To the extent that Abbott argues that what OIG knew about the prices for the subject drugs in connection with its preparation of these two reports is relevant, the United States has already produced a substantial quantum of material on that issue.

The second category of material the Government has submitted to the Court consists of draft documents that relate to a decision by CMS to notify its Medicare carriers in 2000 about the availability of pricing information that had been assembled by DOJ. As with the final version, the draft version of Program Memorandum AB-00-86 has an appended list that includes prices for several of the subject drugs in the instant case. *See* HHC901 0689-0710. The application of the balancing factors to the CMS draft memoranda is similar to our application of them to the OIG draft reports discussed above. The final version of Program Memorandum AB-00-86 has been in the public domain for years and has been produced to Abbott in this case. To the extent that Abbott contends that the price list compiled by DOJ establishes Government knowledge of actual Abbott prices for certain of the subject drugs in 1999 and 2000, Abbott can use the final memorandum and price list as evidence – assuming the Court deems them relevant. Abbott has also deposed CMS personnel about the memorandum. There simply is no need, in light of the issues in the case, for Abbott to invade an important governmental privilege in order to obtain a draft version of a document, the final version of which has been publicly available and well-known within the pharmaceutical industry since it was issued in 2000.

Factors Three and Four - Seriousness of the Issues and Government's Role in Case

The United States recognizes that its allegations that Abbott abused the system in place to determine payment amounts under Government healthcare programs involves a claim of the utmost seriousness. The Government does not concede however, that the arguments put forth by Abbott to invade the deliberative process privilege can survive even facial scrutiny and should be deemed "serious." Abbott states that it requires the information reflected in internal agency documents to demonstrate that the *amicus* brief filed by the Government relating to the legal issue resolved by the Court's November 2006 summary judgement ruling contained factual misstatements and that the Government mislead the Court. Judge Saris, however, determined that she would construe the term "AWP" by its plain language, not on the basis of what particular agency employees thought about the term or in light of how any individual may have used it. To the extent Judge Saris considered other canons of regulatory and statutory construction, her written decision clearly followed the principles set out in *Lachman, supra,* and looked only to the official public record when analyzing regulatory intent. Abbott's argument regarding its purported need for the material is patently spurious, not serious.

Factor Five - Future Affect on Government Employees

As established by the declarations by the Government officials who asserted the deliberative process privilege for the documents at issue and as reflected in case law directly on point, there is a real harm to the Government that would result from the release of these materials.

a. Draft Versions of OIG Reports

The Declaration of Robert Vito, of OIG, describes the harm that would result from the compelled release of draft reports. Mr. Vito sets forth the nature of the inspection work conducted by OIG's Office of Evaluation and Inspections (OEI), and discusses the importance of candid and internal discussion, deliberation, and analysis to the process of conducting and issuing inspection reports. *See* Declaration of Robert A. Vito, ¶ 20 (Ex. 4 to Dkt. No. 4076). A critical part of OEI's work comes in the drafting phase, in which the office engages in substantial internal deliberation about a given report's conclusions, recommendations, and wording. *See id.* at ¶¶ 12-14. Mr. Vito – who has worked with OIG since 1978 – further states that "I have no doubt that if my staff or others within the OIG expected that their comments, criticisms, suggestions, or proposed edits made during our report process to be publicly displayed in the context of a lawsuit, this would stifle much of the very necessary candid dialogue among us. The OIG's work would suffer as a result, to the detriment of HHS programs and the public." *Id*. at ¶ 24.

At least one district court has recognized the need to protect, via the deliberative process privilege, the communications and internal workings of offices of inspectors general. *See Moye, O'Brien, O'Rourke, Hogan, & Pickert v. Nat'l R.R. Passenger Corp*., 376 F.3d 1270, 1279 (11th Cir. 2004) (upholding deliberative process privilege for internal work papers generated by Amtrak's Office of Inspector General in connection with financial and performance audits). Moreover, both the Magistrate Judge and the presiding Judge in this case have recognized the validity of the concerns stated by Mr. Vito given that the deliberative process privilege for the

bulk of the documents on OIG's log has been upheld, both initially by the Magistrate, and by Judge Saris over Abbott's objections.

Given that Abbott has absolutely no need, in the context of the issues which are truly relevant in this case, for drafts of these two OIG reports, the potential chilling effect that the release of these documents would have on OIG's work outweighs Abbott's interest in disclosure.

b. Drafts of Memoranda on Use of Alternative Price Data

Similarly, internal discussion about draft memoranda is an instrumental part of CMS's decision making processes. The Declaration of Leslie Norwalk, former acting administrator of CMS identifies the concern within CMS about the chilling effect on agency deliberations that release of draft documents such as the one submitted to the Court would have. Ms. Norwalk described the key role that candid internal discussion plays in CMS's efforts to set policy consistent with the agency's controlling statutes, regulations, and objectives, and states that CMS employees would feel constrained in offering candid advice if they understood that their views would not be treated as confidential. *See* Declaration of Leslie V. Norwalk, at pp. 17-21 (Ex. 5 to Dkt. No. 4076). The release of draft versions of documents would be detrimental to the decision-making process at CMS and Abbott's demand for it should be rejected in light of defendant's lack of need for the document.

The internal draft CMS memoranda bearing the bates-numbers HHC902-0214 through 0244 is, on its face, clearly a document which lays out policy options relating to the agency's potential use of alternative pricing information for drugs covered by Medicare. The document is marked "ver. 5" on the top of the first page, and contains handwritten marginalia on a number of pages. The subject matter of the document goes to the heart of the deliberative process because it

reflects internal agency deliberations about how to implement a prospective policy change. The deliberations were not Abbott-specific; rather, they involved macro-level discussions about drug payment policy, as well as strategic issues associated with the policymaking process. The document is being submitted for *in camera* review because it lists Medicare allowed amounts, prices compiled by DOJ in or around 1999 and 2000 (sometimes referred to as "the DOJ Prices") and Red Book values, including those for one of the subject drugs in this case.

An application of the balancing test to this document militates against compelled production. Abbott is aware that CMS disseminated the "DOJ Prices" in 2000-2001, and has documents and information reflecting those prices. The remainder of the document is macro-level debate about drug reimbursement, of no specific relevance to Abbott or to the specific issues in the instant case. Abbott's defenses are not assisted by generalized, internal policy discussions about CMS's drug payment systems. This case is not about the Government's consideration of policy alternatives, but rather about Abbott's conduct – a feature of the case recognized by Judge Saris in her November 9, 2007 Order, directing the Government to produce only Abbott-specific materials for *in camera* review. Abbott's need for this document is substantially outweighed by the United States' interest in protecting the confidentiality of the candid, internal advice obtained from agency personnel. Accordingly, the deliberative process privilege as it applies to the CMS draft memoranda should be upheld.

Conclusion

Based on the foregoing, the United States respectfully requests that the Court deny Abbott's motion to compel production of the 21 documents submitted, *in camera* and under seal, concurrent with this memorandum.

Respectfully submitted,

For the United States of America,

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Dated: December 4, 2007

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "MEMORANDUM BY THE UNITED STATES RELATING TO DOCUMENTS SUBMITTED FOR IN CAMERA REVIEW PURSUANT TO THE COURT'S ORDER OF NOVEMBER 9, 2007" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Justin Draycott

Dated: December 4, 2007 Justin Draycott